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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/745,643	12/22/2000	Todd M. Boyce	285-113 CON	1535

7590

02/28/2003

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EXAMINER

PELLEGRINO, BRIAN E

ART UNIT

PAPER NUMBER

3738

DATE MAILED: 02/28/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/745,643

Applicant(s)

BOYCE ET AL.

Examiner

Brian E Pellegrino

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 December 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4-17 and 20-27 is/are pending in the application.
- 4a) Of the above claim(s) 10-17 and 25-27 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4-9 and 20-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/13/02 has been entered.

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1,2,4,5,8,9, 21,24 are rejected under 35 U.S.C. 102(e) as being anticipated by Marino (6290724). Marino shows (Fig. 1A) a "substantially" cylindrical body with at least two tabs **36** longitudinally placed from the two ends of the vertebral implant. The use of "substantially cylindrical body" is terminology of relative degree, which has no basis of comparison. For this reason, it is considered broad and relatively unlimited. It can be seen that the tabs are radially spaced that a first tab is approximately 180° from a second tab on the opposite side. It can also be seen that there is a throughbore **42** which is perpendicular to the longitudinal axis and radially spaced from the tabs. The tabs have a width less than or *equal* to the maximum

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diameter of the body. Marino discloses the implant is formed from bone or material derived from bone, col. 6, lines 31-42. Please note the intended use, as set forth in the claims, carries no weight in the absence of any distinguishing structure. Thus the tabs are fully capable of "possessing a configuration and dimensions of preformed recesses."

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1,2,4-7,9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Godefroy et al. (5683463) in view of Bianchi et al. (6033438). Fig. 6 shows a "substantially" cylindrical body having at least two tabs **16, 14** radially spaced approximately 180° about the body of the implant and have a width at least less than or *equal* to the maximum diameter of the body. It can also be seen there is at least one throughbore **9**. Fig. 1 shows a body portion with one end having an installation slot **24** and a bore **23** between the slot. Please note the intended use, as set forth in the claims, carries no weight in the absence of any distinguishing structure. Thus the tabs are fully capable of "possessing a configuration and dimensions of preformed recesses." However, Godefroy et al. do not disclose the use of bone for the implant. Bianchi et al. teach the advantages of using bone as an implant, i.e., it allows excellent postoperative imaging, col. 2, lines 13-26. Bianchi also teaches that intervertebral implants are made from the bone, col. 5, lines 40-58. Bianchi additionally teaches that bone implants with surface features aid in stabilization and facilitate fusion, col. 8, lines 11,12. It would

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have been obvious to one of ordinary skill in the art to use bone as taught by Bianchi et al. for the implant of Godefroy et al. in order to provide a preserved biological material that is fully capable of being stabilized in the vertebrae while also facilitating fusion.

Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Marino '724 in view of Scarborough (5676146). Marino is explained supra. However, Marino does not disclose the use of animal bone for the implant. Scarborough teaches to use animal bone for an implant, col. 2, lines 13-15 and for vertebral repair, col. 3, lines 11-22. It would have been obvious to one of ordinary skill in the art to use animal bone as taught by Scarborough in the implant of Marino in order to provide a radiolucent material for easier tracking the implant after implantation.

Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Marino '724 in view of Lewandrowski et al. (J. Biomat. Res.). Marino is explained supra. However, Marino does not disclose the surface is demineralized. Lewandrowski et al. teach that demineralization enhances bone osteoinductive properties, p.365. It would have been obvious to one of ordinary skill in the art to use animal bone as taught by Lewandrowski et al. in the implant of Marino in order to provide a prosthesis capable of stabilizing the vertebrae while stimulate bone ingrowth.

Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Marino '724 in view of Kuslich et al. (5445639). Marino is explained supra. Marino discloses forming a core and the implant is positioned by rotating, col. 14, lines 12-26. Marino also discloses implants and the vertebral space that the implant engages are often matched with respect to one another, col. 4, lines 10-24. However, Marino does not

disclose the step of forming a stepped bore in a portion of the vertebrae. Kuslich et al. teach to bore areas for vertebral implants with progressively increased blades that can be interpreted to be a stepped bore form, col. 7, lines 55-66. Fig. 17 shows an enlarged chamber or stepped bore. Kuslich also teaches the stepped bore can be used for dowels or tabs. It would have been obvious to one of ordinary skill in the art to use the method of boring vertebrae in a stepped fashion as taught by Kuslich et al. for inserting the implant of Marino in the implanting procedure in order to provide a ready-made chamber that would not require any forceful rotation or positioning.

Response to Arguments

Applicant's arguments filed 12/13/03 have been fully considered but they are not persuasive. Regarding Applicant's remarks about Godefroy or Marino as not disclosing an implant now claimed to be made from bone, they are moot in view of the new rejection for Godefroy. It is noted that Marino does disclose bone for the implant, col. 6, lines 39-42. Applicant's argument that the claimed device is used differently than the prior art is not persuasive. A claim containing a "recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus" if the prior art apparatus teaches all the structural limitations of the claim. *Ex parte Masham*, 2 USPQ2d 1647 (Bd. Pat. App. & Inter. 1987). In this case, both Marino and Godefroy meet the structural limitations. Additionally, there is no recitation in the claims that define a "thicker" tab than that of Marino. In response to applicant's argument that the references fail to show certain

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features of applicant's invention, it is noted that the features upon which applicant relies (i.e., tabs are sufficiently long enough to engage or access the cancellous bone) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). The claims do not set forth that the placement is consistent or predictable, but only that the device can correspond to a preformed recess. Thus the references anticipate the claims as presented.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Ford et al. (6511509) disclose a spinal implant made of bone.

Pafford et al. (6371988) teach that spinal spacers are made from bone.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Pellegrino whose telephone number is (703) 306-

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5899. The examiner can normally be reached on Monday-Thursday from 9am to 6:30pm. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached at (703) 308-2111. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-2708.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

Brian E. Pellegrino
February 24, 2003
TC 3700, AU 3738

Brian E. Pellegrino


CORRINE McDERMOTT
SUPERVISORY PATENT EXAMINER
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